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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/963,676	09/27/2001	Yem Chin	BSX-219	8991

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EXAMINER

ROBERTS, PAUL A

ART UNIT	PAPER NUMBER
3731	

DATE MAILED: 02/11/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	09/963,676	CHIN ET AL.
	Examiner	Art Unit
	Paul A Roberts	3731

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

**A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM  
 THE MAILING DATE OF THIS COMMUNICATION.**

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1) Responsive to communication(s) filed on Jan 17, 2003.

2a) This action is **FINAL**.                            2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4) Claim(s) 1-34 is/are pending in the application.

4a) Of the above claim(s) 4, 8, 15, 19, 24, 30, and 33 is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 1-3, 5-7, 9-14, 16-18, 20-23, 25-29, 31-32, and 34 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.  
 If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
 \* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
 a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) Notice of References Cited (PTO-892)  
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  
 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3.

4) Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_.  
 5) Notice of Informal Patent Application (PTO-152)  
 6) Other: \_\_\_\_\_

**DETAILED ACTION**

***Election/Restrictions***

This application contains claims directed to the following patentably distinct species of the claimed invention:

Group I: those claims drawn to the needle knife configuration as shown in figure 11

Group II: those claims drawn to the sphincterotome wire configuration as shown in figure 12.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1, 6, 12, 17, 21, 27, and 31 appear generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the

examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

During a telephone conversation with Steven War on Jan 17, 2003 a provisional election was made without traverse to prosecute the invention of Group I, claims 1-3, 5-7, 9-14, 16-18, 20-23, 25-29, 31-32, and 34. Affirmation of this election must be made by applicant in replying to this Office action. Claims 4, 8, 15, 19, 24, 30, and 33 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

### ***Claim Objections***

1. Claim 13 is objected to because of the following informalities: Line 3 has a typographical error. The examiner suggests changing “o” to “of.” Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 28, 29, 30, 32, and 33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which

applicant regards as the invention. Claims 28, 29, 30, 32, and 33 are dependent upon the incorrect claims. Appropriate correction required or a comment indicating claims were correct as written.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1, 2, 3, 5, 6, 7, 9, 27, 28, 29, 31, and 32 are rejected under 35 U.S.C. 102(e) as being anticipated by Farascioni et al. US 6,142,955 assuming for this all subsequent rejections that claim 28 is dependent on 27, 29 on 28, 30 on 29, 32 on 31, and 33 on 31.

3. Regarding claim 1, Farascioni discloses an endoscopic needle knife with radiopaque markings along the length of the cutting member (figure 8; col. 15, 20-23.)

4. Regarding claims 2, 3, 6, 7, 27, 28, 29, 31, and 32, the lines shown in figure 8 act as reference points to determine the length of the deployed cutting member.

5. Regarding claims 5 and 9, the method step, “referencing the middle of the cutting member...,” is not given any patentable weight since the step fails to recite any structural

limitations. However, the Farascioni device is capable of being referenced in the aforementioned manner.

6. Claims 10, 11, 21, 22, 23, 25, and 34 are rejected under 35 U.S.C. 102(b) as being anticipated by Werner US 5,779,724. Werner discloses a surgical endoscopic catheter containing a needle knife on the end. The catheter shown in figure 2 contains evenly spaced detents (50), which interact with notch (64) on the distal end. The cable actuation is brought forth by spring 58, figure 5.

7. Regarding claims 21, 22, 23, and 34, the cutting member has detents (50), which also act as a visual indicator as to extent of extension of the surgical blade.

8. Regarding claim 25, the method step, “referencing the middle of the cutting member...” is not given any patentable weight since the step fails to recite any structural limitations. However, the Werner device is capable of being referenced in the aforementioned manner.

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 12, 13, 14, 16, 17, 18, and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Werner '724 in view of Farascioni et al '955. Werner discloses a surgical endoscopic catheter containing a needle knife on the end. The catheter contains evenly spaced detents (50), which interact with one notch (64) on the distal end. Werner fails to disclose an

endoscopic needle knife with radiopaque markings along the length of the cutting member.

Farascioni teaches an endoscopic needle knife with radiopaque markings along the length of the cutting member (figure 8; col. 15, 20-23.) Farascioni states the motivation for including the radiopaque markings is that they would “indicate the longitudinal spacing of tissue basket 434 in order to provide the user with an indication of the tissue sampling area.” At the time of the invention it would have been obvious to modify the Werner surgical catheter by including the radiopaque markings as taught by Farascioni for the purpose of providing “the user with an indication of the tissue sampling area”

10. Regarding claims 13, 14, 17, and 18, the lines, shown in figure 9, act as reference points to determine the length of the deployed cutting member.

11. Regarding claims 16 and 20, the method step, “referencing the middle of cutting member...” is not given any patentable weight since the step fails to recite any structural limitations. However, the Werner device is capable of being referenced in the aforementioned manner.

12. Claim 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over Farascioni et al. ‘955 in view of Dretler et al. WO 01/01869 A1. Farascioni et al. disclose all of claim 21, but do not disclose that the visual indicia should include different color markings. Dretler et al. teach a visualizing indication system on an endoscopic tool (10-15, pg. 11), wherein “those markings assist the user in determining whether the helical coil [knife] is with or without sheath [extended or contracted.]” Thus providing the user a visual indicator of the knife’s position. At the time of the invention, it would have been obvious to one of ordinary skill in the art to modify the

Farascioni et al. device to include colored visual indicia for the purpose of assisting the user in determining whether the knife's position and level of extension.

***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

US 5810807 A "A sphincterotome with deflectable cutting plane and method of using the same."

US 5968061 A "Endoscopic surgical instrument for the implementation of endoscopic surgical procedures."

US 5951580 A "Scalpel having two blades adjustably separable."

US 6290721 B1 "Tubular medical endoprostheses"

US 6497709 B1 "An endoprosthetic filter system"

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul A Roberts whose telephone number is (703) 305-7558. The examiner can normally be reached on 7:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Milano can be reached on 703-308-2496. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3590 for regular communications and (703) 305-3590 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.



Paul Roberts  
February 6, 2003



MICHAEL J. MILANO  
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